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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,221	11/20/2003	Kim Seah Goh	303798 46623	9025

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Pillsbury Winthrop LLP  
Intellectual Property Group  
Suite 2800  
725 South Figueroa Street  
Los Angeles, CA 90017-5406

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/718,221	<b>Applicant(s)</b> GOH, KIM SEAH	
	<b>Examiner</b> Christopher D. Koharski	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

Examiner acknowledges that no information disclosure statement (IDS) was filed with this application; accordingly, the examiner is not considering any information disclosure statements filed at this time.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8-10, 20-21, 23-25 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam (5,382,240). Lam discloses a winged needle cannula guard.

Regarding claims, 1, 3-5, 8-10, 20-21, 23-25 and 28-30, Lam discloses a cannula guard comprising a hub (20) with an axial hole therethrough, cannula (12) with a beveled edge (28), a cylindrical sleeve (18) capable of rotation within a cylindrical sheath (22) with openings (24), pair of flexible wings (26), connection tubing (14), and first and second locking system (Figures 1-8). Wherein the locking mechanism comprises a two-part system that releasably locks the sheath into a first position and unreleasably locks the sheath into a second position (Figures 5-8) via several annular rings/ribs (for the sheath to slide over) and locking lugs that include angled edges and

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solid face edges to achieve the sheath locking capability. The locking tabs are attached with a hinge (24) type member to allow for movement.

***Claim Rejections - 35 USC § 102***

Claims 11-14, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu (5,931,815). Liu discloses a multifunction safety infusion set with a needle protection sheath.

Regarding claims 11-14, 16 and 18, Liu discloses an infusion set comprising a hub (31) with an axial hole therethrough, a cannula (32) with a beveled edge (3A), flexible wings (43), connection tubing (2), a cylindrical sleeve (1), a cylindrical sheath (40) for retaining the assembly therein in which the hub, sleeve and sheath are capable of being rotated in relation to each other (Figure 1). Additionally a locking system comprising a two-part system that lock the sheath into a first position and a second telescopic position which protectively covers the cannula through the use of locking tabs and annular rings (Figures 2-5).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 15 and 26 are rejected under 35 U.S.C 103(a) as being unpatentable over Lam or Liu in view of Tal (US2003/0153874). Lam and Liu meet the claim limitations as described above except for the use of a marking to indicate the needle orientation.

However, Tal teaches a vascular access device.

Regarding claims 6, 15 and 26, Tal teaches the use of indicating marks of various markings (color coding, words, other marks), which indicate the needle bevel level and the needle position within the assembly ([0014]).

At the time of the invention, it would have been obvious to add the indicating markings of Tal to the systems of Lam or Liu because the addition of the indicating markings allows control and feedback to the user regarding needle position. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Tal.

### ***Claim Rejections - 35 USC § 103***

Claims 2, 7, 22 and 27 are rejected under 35 U.S.C 103(a) as being unpatentable over Lam or Liu in view of Maclean Crawford et al. (6,659,984). Lam and Liu meet the claim limitations as described above except for the specific openings and locking tabs located in the outer cylindrical sheath.

However, Maclean Crawford et al. teaches a needle safety assembly.

Regarding claims 2, 7, 22 and 27, Maclean Crawford et al. teaches a needle assembly with an outer cylindrical sheath with two openings (68, 72) that provides a locking mechanism with locking tabs (70, 42) (Figures 1-3).

At the time of the invention, it would have been obvious to include the locking system of Maclean Crawford et al. to the systems of Lam or Liu because the addition of this external locking system allows the user to view the needle hub/sleeve position through the openings. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Maclean Crawford et al.

Additionally, Examiner asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the locking mechanism of Lam or Liu with the openings and locking tabs in the cylindrical sheath, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

### ***Claim Rejections - 35 USC § 103***

Claims 17 and 19 are rejected under 35 U.S.C 103(a) as being unpatentable over Liu in view of Lam. Liu meets the claim limitations as described above except for supportive tabs and a hinged tabs.

However, Lam teaches Lam discloses a winged needle cannula guard.

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Regarding claims 17 and 19, Lam teaches a needle locking system that uses several annular rings/ribs (for the sheath to slide over) and locking lugs that include angled edges and solid face edges to achieve the sheath locking capability; the locking tabs are attached with a hinge (24) type member to allow for movement (figures 5-8).

At the time of the invention, it would have been obvious to include the supportive ribs and hinged members of Lam to the system of Liu because the addition of supportive ribs allows for easier sliding of the sheath and the hinged member allows for controlled locking and facilitates sheath movement. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Lam.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 11/15/2006

  
Christopher D. Koharski  
AU 3763

  
